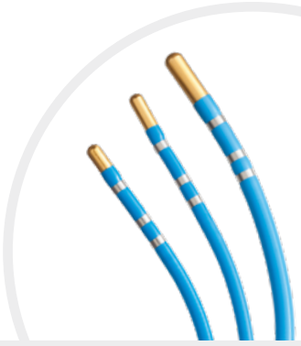
Medtronic

The Freezor™ Family of Cardiac Cryoablation Catheters



The Freezor family of cardiac cryoablation catheters are flexible, single-use, minimally invasive devices designed to ablate cardiac tissue. The Freezor family of catheters, used in conjunction with the CryoConsole™, are the only focal catheters that utilize the cryo energy source.

The Freezor family of catheters consists of three different focal cryoablation catheters: Freezor™, Freezor™ *Xtra*, and Freezor™ *MAX*. These single-use catheters are flexible, steerable devices specifically designed for ablating cardiac tissue.

Two tip sizes (Freezor with 4 mm and Freezor *Xtra* with 6 mm) are available on a 7 Fr diameter shaft, and Freezor *MAX* with an 8 mm tip size is available on a 9 Fr diameter shaft. All of the different tip sizes have multiple reaches. A thermocouple is integrated into each tip for temperature monitoring.

The various combinations of diameters, tip sizes, and reaches provide physicians with the flexibility they need to ablate a broad range of target cardiac arrhythmias – with ablation indications ranging from AVNRT for pediatric† and adult patients (Freezor and Freezor *Xtra* catheters) to atrial arrhythmias for adult patients (Freezor *MAX* catheters).

†Indicated for patients over two years of age.

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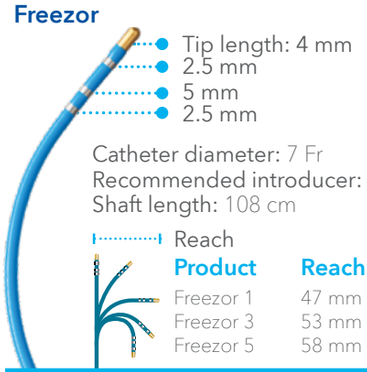
Product specifications

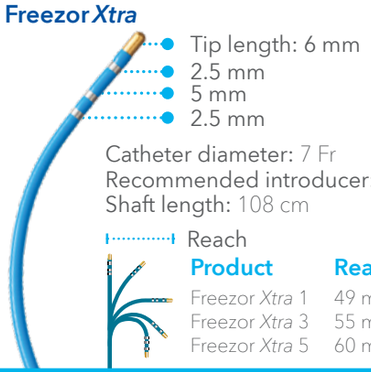
Freezor



Catheter diameter: 7 Fr
Recommended introducer: 8 Fr
Shaft length: 108 cm

Product	Reach
Freezor 1	47 mm
Freezor 3	53 mm
Freezor 5	58 mm

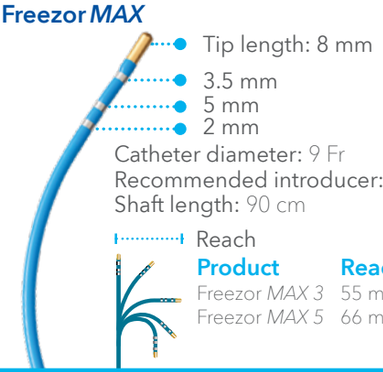
Freezor *Xtra*



Catheter diameter: 7 Fr
Recommended introducer: 8 Fr
Shaft length: 108 cm

Product	Reach
Freezor *Xtra* 1	49 mm
Freezor *Xtra* 3	55 mm
Freezor *Xtra* 5	60 mm

Freezor *MAX*



Catheter diameter: 9 Fr
Recommended introducer: 10 Fr
Shaft length: 90 cm

Product	Reach
Freezor *MAX* 3	55 mm
Freezor *MAX* 5	66 mm

Freezor	Freezor *Xtra*	Freezor *MAX*
Size		
Tip length		
4 mm	6 mm	8 mm
Electrode spacing		
2.5-5-2.5	2.5-5-2.5	3.5-5-2
Catheter diameter		
7 Fr	7 Fr	9 Fr
Shaft length		
108 cm	108 cm	90 cm
Reach		
47 mm 53 mm 58 mm	49 mm 55 mm 50 mm	55 mm 66 mm
Compatibility		
Recommended compatible introducer		
8 Fr	8 Fr	10 Fr
Order number		
207F1 207F3 207F5	217F1 217F3 217F5	209F3 209F5

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Brief Statements

Freezor™ Cardiac Cryoablation Catheter

Indications (or Intended Use): The Freezor Cardiac Cryoablation Catheter, CryoConsole System, and related accessories are indicated for the cryoablation of the conducting tissues of the heart in the treatment of adult and pediatric patients over 2 years of age, with atrioventricular nodal reentrant tachycardia (AVNRT).

Contraindications: This device is contraindicated in patients with active systemic infection, cryoglobulinemia, intracardiac mural thrombus, myxoma, interatrial baffle or patch.

Warnings and Precautions: Closely monitor AV conduction during cryo energy delivery near the AV node due to possible risk of complete atrioventricular (AV) block. Immediately terminate energy delivery if partial or complete AV block is noted. Cryoablation involving coronary vessels has been associated with subsequent clinically significant arterial stenosis. Care should be taken to minimize unnecessary contact with coronary vessels during cryoablation. Endotoxins may cause pyrogenic responses in patients including inflammation and fever which can result in anaphylactic shock and death. Caution should be used with regard to endotoxins in pediatric populations as standard endotoxin limits do not differentiate between adult and pediatric populations. Ethylene Oxide residuals remaining after sterilization are known to cause a potential increase in a number of biological effects including irritation, organ damage, mutagenicity and carcinogenicity. Calculations for ethylene oxide and ethylene chlorohydrin residuals indicate that the risk of these effects may be increased in patients under 3.8kg. Avoid catheter entanglement with other catheters devices or wires. Closely monitor patients undergoing cardiac ablation procedures during the post-ablation period for clinical adverse events. Do not re-use, reprocess or resterilize this device for purpose of reuse. This device is intended only to be used once
for a single patient. The use of CryoMapping mode does not prevent injuries to the patient. CryoMapping mode is used to determine if the site is appropriate for ablation. The Freezor Catheter contains a pressurized refrigerant during operation. Release of this gas into the circulatory system due to equipment failure or misuse could result in gas embolism. Do not pull on the catheter, sheath, umbilical cables, or console while the catheter tip is frozen to the tissue, as this may lead to tissue injury. Always advance and withdraw components slowly to minimize the vacuum created and therefore minimize the risk of air embolism. Do not connect the Freezor Catheter to any radiofrequency generator or use the Freezor Catheter to deliver RF ablation energy. Before powering up an RF generator of applying RF energy, disconnect the cryoablation catheter from the CryoConsole. The use of fluoroscopy during catheter ablation procedures presents the potential for significant x-ray exposure to both patients and laboratory staff. Give careful consideration before using the device in pregnant women.

Avoid positioning the catheter around the chordae tendineae, as this increases the likelihood of catheter entrapment within the heart. Do not pass the catheter through a prosthetic heart valve (mechanical or tissue).

Catheter handling: • Use extreme care when manipulating the catheter. Lack of careful attention can result in injury such as perforation or tamponade. • Do not use excessive force to advance, withdraw, the catheter, especially if resistance is encountered. • Do not use the catheter if it is kinked, damaged, or cannot be straightened. • Straighten the cooling segment before inserting or withdrawing the catheter. • Do not at any time preshape or bend the catheter shaft or cooling segment. • Catheter advancement should be performed under fluoroscopic guidance or other appropriate visualization technique.

Use only isolated equipment (IEC 60601-1 Type CF equipment, or equivalent) with the CryoConsole and catheters. The Medtronic cryoablation catheters, refrigerant tanks, and other Medtronic CryoConsole components should only be used with the Medtronic CryoConsole. If the sterile packaging or catheter is damaged, do not use the catheter. This equipment should be used only by physicians that perform cardiac ablation. Do not expose the catheter handle or coaxial and electrical connectors to fluids or solvents. Disconnect the catheter's electrical connection prior to cardioversion/defibrillation. Administer appropriate levels of peri-procedural anticoagulation therapy for patients undergoing right-sided procedures. The Freezor catheter has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. Scanning a patient during the use of this device may result in patient injury.

Potential Adverse Events or Potential Complications: Potential complications that may be associated with cardiac catheterization and ablation listed alphabetically below include, but are not limited to: Access site complications including, hematoma, infection, thrombosis, ecchymosis, AV fistula, bleeding from puncture site, hemorrhage; arrhythmias (such as atrial fibrillation, atrial flutter, tachycardia); cardiac arrest and/or death; chest discomfort, pain or pressure; coronary artery spasm/stenosis; damage to heart tissue or vasculature; endocarditis; entrapment; heart block,requiring permanent pacemaker; hemothorax; infection; perforation of venous, cardiac or surrounding tissue, pericardial effusion, tamponade; pericarditis; phrenic nerve injury; pleural effusion; pneumothorax; pseudoaneurysm; pulmonary edema; pulmonary embolism; stroke; tissue infarction (such as myocardial infarction or renal infarction); thrombus; transient ischemic attack; vagal nerve injury (such as gastroparesis); vasovagal reaction

Refer to the device technical manual for detailed information regarding the procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult the Medtronic website at medtronic.com.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

Freezor *Xtra*™ Cardiac Cryoablation Catheter

Indications (or Intended Use): The Freezor *Xtra* Cardiac Cryoablation Catheter, CryoConsole system, and related accessories are indicated for the cryoablation of the conducting tissues of the heart in the treatment of adult and pediatric patients over 2 years of age with atrioventricular nodal reentrant tachycardia (AVNRT). The Freezor Xtra catheter is also intended for minimally invasive cardiac surgery procedures, including surgical treatment of cardiac arrhythmias. The Freezor *Xtra* catheter freezes the target tissue and blocks the electrical conduction by creating an inflammatory response or cryonecrosis

Contraindications: The Freezor *Xtra* Cardiac Cryoablation Catheter is contraindicated in patients with the following conditions: • Active systemic infections • Cryoglobulinemia • intracardiac mural thrombus • myxoma • interatrial baffle or patch

Warnings and Precautions: Do not reuse, reprocess, or resterilize this catheter for purpose of reuse. This catheter is intended only to be used once for a single patient. Closely monitor AV conduction during cryo energy delivery near the AV node due to possible risk
of complete atrioventricular (AV) block. Immediately terminate energy delivery if partial or complete AV block is noted. The use of CryoMapping mode does not prevent injuries to the patient. CryoMapping mode is used to determine if the site is appropriate for
ablation. The catheter contains pressurized refrigerant during operation. Release of this gas into the body or circulatory system due to equipment failure or misuse could result in gas embolism, pericardial tamponade, tissue emphysema, or other patient injury. Always advance and withdraw components slowly to minimize the vacuum created and therefore minimize the risk of air embolism. Endotoxins may cause pyrogenic responses in patients including inflammation and fever which can result in anaphylactic shock and death. Caution should be used with regard to endotoxins in pediatric populations as standard endotoxin limits do not differentiate between adult and pediatric populations. Ethylene Oxide residuals remaining after sterilization are known to cause a potential increase in a number of biological effects including irritation, organ damage, mutagenicity, and carcinogenicity. Calculations for ethylene oxide and ethylene chlorohydrin residuals indicate that the risk of these effects may be increased in patients under 3.8kg. Avoid catheter entanglement with other catheters, devices, or wires. Closely monitor patients undergoing cardiac ablation procedures during the post-ablation period for clinical adverse events. Do not pull on the Freezor *Xtra* catheter, sheath, umbilical cables, or console while the catheter is frozen to the tissue, as this may lead to tissue injury. Do not connect the Freezor *Xtra* catheter to a radiofrequency (RF) generator or use it to deliver RF ablation energy. Before powering up an RF generator or applying RF energy, disconnect the cryoablation catheter from the CryoConsole. The use of fluoroscopy during ablation procedures presents the potential for significant x-ray exposure to both patients and laboratory staff. Give careful consideration before using the device in pregnant women.

Catheter handling: • Use extreme care when manipulating the catheter. Lack of careful attention can result in injury such as perforation or tamponade. • Do not use excessive force to advance or withdraw the catheter, especially if resistance is encountered. • Do not use the catheter if it is kinked, damaged, or cannot be straightened. • Straighten the cooling segment before inserting or withdrawing the catheter. • Do not at any time preshape or bend the catheter shaft or cooling segment. • Catheter advancement should be performed under fluoroscopic guidance or other appropriate visualization technique.

Use only isolated equipment (IEC 60601-1 Type CF equipment, or equivalent) with the CryoConsole and catheters. The Freezor *Xtra* catheter has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. Scanning a patient during the use of this device may result in patient injury. The Medtronic cryoablation catheters, refrigerant tanks, and other Medtronic CryoConsole components should only be used with the Medtronic CryoConsole. If the sterile packaging or catheter is damaged, do not use the catheter. Do not expose the catheter handle or coaxial and electrical connectors to fluids or solvents. Disconnect the catheter's electrical connection prior to cardioversion/defibrillation. Cryoablation involving coronary vessels with liquid nitrous oxide systems has been associated with subsequent clinically significant arterial stenosis. Care should be taken to minimize unnecessary contact with coronary vessels during cryoablation.

Avoid positioning the catheter around the chordae tendineae, as this increases the likelihood of catheter entrapment within the heart. Do not pass the catheter through a prosthetic heart valve (mechanical or tissue). Administer appropriate levels of peri-procedural anticoagulation therapy for patients undergoing endocardial right-sided procedures. This equipment should be used only by physicians that perform cardiac ablation.

Potential Adverse Events or Potential Complications: Potential complications that may be associated with cardiac catheterization and ablation include, but are not limited to: Access site complications including, hematoma, infection, thrombosis, ecchymosis, AV fistula, bleeding from puncture site, hemorrhage; arrhythmias (such as atrial fibrillation, atrial flutter, tachycardia); cardiac arrest and/or death; chest discomfort, pain or pressure; coronary artery spasm/stenosis; damage to heart tissue or vasculature; endocarditis; entrapment; heart block, requiring permanent pacemaker; hemothorax; infection; perforation of venous, cardiac or surrounding tissue, pericardial effusion, tamponade; pericarditis; phrenic nerve injury; pleural effusion; pneumothorax; pseudoaneurysm; pulmonary edema; pulmonary embolism; stroke; tissue infarction (such as myocardial infarction or renal infarction); thrombus;
transient ischemic attack; vagal nerve injury (such as gastroparesis); vasovagal reaction

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Freezor™ *MAX* Cardiac Cryoablation Catheter

Indications (or Intended Use): The Freezor™ *MAX* Cardiac Cryoablation Catheter is used as an adjunctive device in the endocardial treatment of paroxysmal and persistent atrial fibrillation (episode duration less than 6 months)
in conjunction with the Arctic Front™ family of cardiac cryoablation catheters for the following uses: 1) Gap cryoablation to complete electrical isolation of the pulmonary
veins 2) Cryoablation of focal trigger sites and 3) Creation of ablation line between the inferior vena cava and the tricuspid valve.

Contraindications: Use of Freezor™ *MAX* Cardiac Cryoablation Catheter is contraindicated in patients with active systemic infections, in patients with cryoglobulinemia,
intracardiac mural thrombus, myxoma or interatrial baffle or patch. The Freezor *MAX* Cardiac Cryoablation Catheter is also contraindicated in patients with a body mass under 4.4 kg.

Warnings/Precautions: Do not reuse or reprocess this device for purpose of reuse. This catheter is intended only to be used once for a single patient. Do not connect the cryoablation catheter to a radiofrequency (RF) generator or use it to deliver RF energy. Disconnect the catheter's electrical connection prior to cardioversion/defibrillation.

Catheter handling: • Use extreme care when manipulating the catheter. Lack of careful attention can result in injury such as perforation or tamponade. • Do not use excessive force to advance, withdraw the catheter, especially if resistance is encountered. • Do not use the catheter if it is kinked, damaged, or cannot be straightened. Straighten the cooling segment before inserting or withdrawing the catheter. • Do not at any time preshape or bend the catheter shaft or cooling segment. • Catheter advancement should be performed under fluoroscopic guidance or other appropriate visualization technique.

Avoid positioning the catheter around the chordae tendineae. The catheter contains pressurized refrigerant during operation. Release of this gas into the circulatory system due to equipment failure or misuse could result in gas embolism. Do not pass the catheter through a prosthetic heart valve (mechanical or tissue). Use adequate fluoroscopic visualization or other appropriate visualization technique during a transaortic approach to avoid placing the ablation catheter within the coronary vasculature.

Do not pull on the catheter, sheath, umbilical cables, or console while the catheter is frozen to the tissue, as this may lead to tissue injury. Always advance and withdraw components slowly to minimize the vacuum created.

Closely monitor AV conduction during cryo energy delivery near the AV node due to possible risk of complete atrioventricular block.

Perform cryoablation procedures only within the environmental parameters. Do not expose the catheter handle or coaxial and electrical connectors to fluids or solvents.

The use of fluoroscopy during catheter ablation procedures presents the potential for significant x-ray exposure to both patients and laboratory staff. Give careful consideration before using the Freezor™ *MAX* catheter in pregnant women. Use only isolated equipment (IEC 60601-1 Type CF equipment, or equivalent) with the CryoConsole and catheters. The safety of the catheter in the MR environment is unknown (such as any heating, migration, or image artifacts). Scanning a patient during the use of this device may result in patient injury. Avoid catheter entanglement with other catheters, devices, or wires.

Closely monitor patients undergoing cardiac ablation procedures during the post-ablation period for clinical adverse events. Before powering up an RF generator or applying RF energy, disconnect the cryoablation catheter from the CryoConsole. If the device is damaged or the integrity of the sterilization barrier has been compromised, do not use the product. The Medtronic cryoablation catheters, refrigerant tanks, and other Medtronic CryoConsole components should only be used with the Medtronic CryoConsole.

The Freezor MAX catheter was not studied for safety of changes in anticoagulation therapy in patients with paroxysmal atrial fibrillation. This equipment should be used only by physicians that perform cryoablation procedures. Cryoablation procedures should be performed only in a fully equipped facility.

Potential Adverse Events or Potential Complications: Potential complications/adverse events from cardiac catheterization and ablation include, but are not limited to the following: Access site complications including, hematoma, infection, thrombosis, ecchymosis, AV fistula, bleeding from the puncture site, hemorrhage; arrhythmias (such as atrial fibrillation, atrial flutter, tachycardia); cardiac arrest; chest discomfort, pain or pressure; coronary artery spasm/stenosis; damage to heart tissue or vasculature; death; endocarditis; entrapment; esophageal damage (such as atrioesophageal fistula); heart block, potentially requiring implantation of a permanent pacemaker; hemothorax; infection; perforation of venous, cardiac or surrounding tissue, pericardial effusion, tamponade; pericarditis; phrenic nerve injury; pleural effusion; pneumothorax; pseudoaneurysm; pulmonary edema; pulmonary embolism; stroke; tissue infarction (such as myocardial infarction or renal infarction); thrombus; transient ischemic attack; vagal nerve injury (such as gastroparesis); vasovagal reaction

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